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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/554,844	09/19/2000	Volker Zimmer	RDID0044US	9010
32842	7590	05/03/2005	EXAMINER	
THE LAW OFFICE OF JILL L. WOODBURN, L.L.C. JILL L. WOODBURN 128 SHORE DR. OGDEN DUNES, IN 46368			CHIN, CHRISTOPHER L	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 05/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/554,844

Applicant(s)

ZIMMER ET AL.

Examiner

Christopher L. Chin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2005.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,3,5,7-10,13,16,17,20-23,25-35 and 37-45 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 2,3,5,7-10,13,16,17,20-23,25-35, and 37-45 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. Claims 13, 37-40, and 45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 is vague. The claim apparently is claiming a method for detecting the presence of an analyte in the test element of claim 41 but the preamble is directed to a "use". It is suggested that Applicants amend the preamble to reflect a method of detecting the presence of an analyte in a liquid and not a "use" of an analytical test element. The last part of the claim is vague and indefinite as to that "changes" in the detection element are being detected to indicate the presence of analyte.

Claim 45 is vague and indefinite because the last part of the claim is vague and indefinite as to that "changes" in the detection element are being detected to indicate the presence of analyte.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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3. Claims 2-3, 7-10, 13, 16, 17, 20-23, 26, 27, 29-35, and 36-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamada (US Patent 5,399,316) in view of Hodges et al (US Patent 5,942,102) and Zimmer et al (US Patent 5,814,522) for the reasons of record in the previous office action.

In response to this rejection, Applicants argue that Yamada fails to disclose a detection element having a surface facing the carrier that defines a capillary channel and wherein that detection element includes at least one reagent contained therein. Applicants further argue that Yamada holds liquid in the reaction region (21) unlike the instant invention and thus teaches away from the instant invention.

Applicant's arguments have been considered but are not convincing. The detection element of the instant invention was discussed in page 3 of the previous office action. Reaction region (21) of Yamada and the reagents therein is considered to read on the detection element of the instant invention. It should be noted that the instant claims only require the detection element contain at least one reagent. The instant claims do not recite any other limitation on the location of the reagent(s) in the detection element. Whether the reagent is situated on the base member (11), the spacers (12) and (13) or the cover (17) in Yamada is immaterial since the instant claims fail to exclude any of these possible sites for placement of the reagents.

With respect to Applicant's argument that Yamada teaches away from the instant invention, liquid can penetrate the detection region (21) as it flows into the reaction region as in the instant invention and while liquid can be held in the reaction region of Yamada, liquid can exit the reaction region with the aid of the absorbent member (28).

Applicants also present arguments concerning the Hodges and Zimmer references. However, it is noted that Applicants are addressing these references separately without considering the combined teaches of Yamada, Hodges et al, and Zimmer et al. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

4. Claims 5 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamada (US Patent 5,399,316) in view of Hodges et al (US Patent 5,942,102) and Zimmer et al (US Patent 5,814,522) as applied to claims 2-3, 7-10, 13, 16, 17, 20-23, 26, 27, 29-35, and 36-45 above, and further in view of Heller et al (US Patent 6,238,624) for the reasons of record in the previous office action.

In response to this rejection, Applicants argue that Heller et al fails to cure the inadequacies of Yamada, Hodges et al, and Zimmer et al.

Applicant's argument has been considered but is not convincing because Applicant's argument is not directed to the combined teachings. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Double Patenting

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5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 2-3, 5, 7-10, 13, 16, 17, 20-23, 25-35, and 37-45 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,592,815. Although the conflicting claims are not identical, they are not patentably distinct from each other for the reasons of record in the previous office action.

In response to this rejection, Applicants argue that the two sets of claims do not read on each other.

Applicant's argument has been considered but is not convincing because Applicants did not specify how the two sets of claims are different from each other. Aside from asserting that the two sets of claims do not read on each other, no specific differences between the two sets of claims are pointed out.

Conclusion

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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher L. Chin whose telephone number is (571) 272-0815. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Christopher L. Chin
Primary Examiner
Art Unit 1641

5/1/05